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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,423	09/17/2003	Guy A. Rouleau	GOUD:023USD2	3952

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EXAMINER	
KOLKER, DANIEL E	

ART UNIT	PAPER NUMBER
1649	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/664,423	ROULEAU ET AL.	
	Examiner	Art Unit	
	DANIEL KOLKER	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 November 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14,17,20,25,30-34,39 and 40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14,17,20,25,31,39 and 40* is/are rejected.

7)☒ Claim(s) *30,32-34* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The remarks and amendments filed 19 November 2008 have been entered. Claims 14, 17, 20, 25, 30 - 34, and 39 - 40 are pending and under examination.

Maintained Rejections and Objections

Priority

2. Applicant is reminded that the effective filing date of all claims encompassing the D188V mutation is the date that parent application 09/718355 was filed, namely 24 November 2000. As set forth at pp. 3 - 4 of the office action mailed 19 June 2008, the D188V mutation was first disclosed in the '355 application and was not disclosed in provisional application 60/167623. Applicant did not traverse the examiner's determination that D188V was first disclosed in the '355 application, and did not traverse the examiner's determination that all claims which do not recite the D188V mutation are entitled to 26 November 1999 as the effective filing date.

Due to applicant's amendments, claims 14, 25, and 32 now recite the D188V mutation. Accordingly, these claims as well as dependent claims 17, 20, and 39 - 40 have an effective filing date of 24 November 2000. The following table indicates the effective filing date of each claim.

Claim Number	Effective Filing Date
14, 17, 20, 25	24 November 2000
30, 31	26 November 1999
32	24 November 2000
33, 34	26 November 1999
39, 40	24 November 2000

Should applicant disagree with the examiner's factual determination, applicant should provide evidence or point to evidence currently of record which indicates that the provisional application provides support for the D188V limitation recited in claims 14, 17, 20, 25, 32, and 39 - 40. This could be accomplished, for example, by pointing to specific page and line numbers or to figures or sequences in the 60/167623 application where this mutation is disclosed.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 14, 17, 20, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Noda (1987. Journal of Receptor Research 7:467-497) in view of Wood (WO 97/01577, published 16 January 1997), Malo (1994. Cytogenet Cell Genet 67:178-186, cited as reference C45 on IDS filed 10 November 2003), and Current Protocols in Molecular Biology (1989 – 1996, pages 6.0.3 – 6.0.5, 6.1.1 – 6.1.4, 6.3.1 – 6.3.6, and 6.5.1 – 6.5.2).

This rejection is maintained for the reasons previously made of record. The places where each reference teaches the relevant claim limitations have been set forth in the office action mailed 19 June 2008 and for the sake of brevity will not be repeated herein. Briefly, Noda teaches a nucleic acid encoding rat sodium channel. The sequence from Noda encodes a protein that is 98.6% identical to the protein of SEQ ID NO:3; see previously-mailed sequence alignment. The reference is therefore on point to claims 14 and 31, which encompass nucleic acid encoding SEQ ID NO:3 (see claim 14 part(c)(i)). Noda teaches vectors and cells carrying the nucleic acids encoding this protein; see p. 469, which is relevant to claims 17 and 20. However Noda does not explicitly teach a nucleic acid encoding SEQ ID NO:3, as recited in claims 14 and 31.

Wood teaches a number of screening methods with recombinant sodium channels, and teaches that they are useful for identifying new drugs. Wood also teaches that when a sodium channel from one species is known, and the nucleic acid encoding the channel is in hand, one

can screen a cDNA library made from a second species in order to obtain the nucleic acid encoding the same protein from the second species. Note that Wood indicates while certain examples discuss rat sequences, human sequences can also be used. Wood also teaches alternative methods to identify human sodium channel sequences, by using PCR, and teaches how to confirm that the appropriate clone has been obtained with an *in vitro* assay (p. 28 line 18 – p. 32 line 2). However while Wood teaches these methods relating to sodium channels expressed in the periphery, the reference does not explicitly teach sodium channels encoded by nucleic acids identical to SEQ ID NO:3, as encompassed by claims 14 and 31.

Malo teaches nucleic acids which are partial sequences of human sodium channel 1 alpha, also known as SCN1A. See in particular p. 179 second column ("Results"), Figure 2 on p. 181, p. 182 "Assignment of a human brain sodium channel 1α (SCN1A) gene", and Figure 3, appearing on p. 183, which shows the sequence of the isolated nucleic acid and encoded protein. While the human sequence is obviously only a partial sequence, at both the nucleic acid and amino acid levels, the high degree of homology between the identified human sequences and the rat sequence known in the prior art (Note that Figure 3 from Malo indicates that the rat sequence is that from Noda 1986; this is the same sequence used by Noda 1987, cited above) suggests to the artisan of ordinary skill that the full-length human sequence could be obtained. Malo teaches that the partial sequence was obtained by PCR on a human genomic library (p. 179 first column). However Malo does not teach the full-length sequence of SEQ ID NO:3, or nucleic acids encoding the full-length sequence.

Current Protocols Chapter 6 excerpts teaches the artisan of ordinary skill how to screen a DNA library to obtain clones. The specific techniques and protocols necessary for the experiments are detailed, and troubleshooting tips are presented. Chapter 6.1 teaches the artisan of ordinary skill how to plate libraries and transfer them to filters; Chapter 6.3 teaches how to hybridize a DNA probe to the filters, and Chapter 6.5 provides guidance in isolating the appropriate clone. Note that each of the individual articles was originally published between 1989 and 1996, as indicated by the dates on the face page of each chapter. Thus the reference describes techniques to screen libraries and pull out a full-length clone which were well–known prior to the effective filing date of this invention. However Current Protocols does not teach either sodium channels or screening assays.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to screen a human DNA library in order to obtain a full-length clone encoding SCN1A,

thereby arriving at the invention of claims 14 and 31, with a reasonable expectation of success. The motivation to do so would be to find inhibitors of human sodium channels, instead of rat sodium channels used by Noda. This motivation comes directly from the references themselves; note that Malo teaches that human tissues express SCN1A-encoding nucleic acid, and teaches that such nucleic acids can be obtained by screening libraries. The artisan of ordinary skill would have a reasonable expectation of success in obtaining full-length nucleic acid encoding human SCN1A (i.e., encoding the protein of SEQ ID NO:3), given that Noda provides the full-length rat sequence and Malo provides a partial human sequence. Putting the claimed nucleic acid into vectors and host cells, as in claims 17 and 20, would have also been obvious given the teachings of Noda.

Applicant argues, on p. 8 of the remarks filed 19 November 2008, that obtaining the full-length nucleic acid sequence encoding SEQ ID NO:3 would not have been obvious to one of ordinary skill. Applicant argues that there were "an outrageous number of unpredictable alternatives", and that nothing points to the specific sequences encoding SEQ ID NO:3. Applicant's arguments have been fully considered but they are not persuasive. The reference by Malo clearly indicates that partial sequences of the human nucleic acid were known. Obtaining the rest of the human sequence would not have been the result of innovation, but of routine work and experimentation. At the time the invention was made, obtaining full-length cDNAs once a probe or partial sequence was in hand was routine. The methods to obtain such full-length cDNAs were described in Current Protocols, a standard laboratory manual.

The present fact pattern is similar to that in *Ex Parte Kubin* (83 USPQ 2d 1410, Bd Pat App & Int 2007; note a copy of the decision is available at the USPTO's website, the address is http://www.uspto.gov/web/offices/dcom/bpai/prec/fd070819.pdf). In *Kubin*, the Board upheld the Examiner's position that obtaining a full-length nucleic acid by cloning methods would have been obvious. See in particular pp. 7 - 10 of the Board's decision (as published on the USPTO website). Note that the Board determined that given the Supreme Court's recent decision in *KSR v. Teleflex* (127 S. Ct. 1727), the "obvious to try" rationale can be applied; see also MPEP § 2143, subsection E, Example 3. The examiner has concluded that given the teachings of the prior art references, it would have been obvious to one of ordinary skill in the art to follow the guidance in Current Protocols to obtain the human cDNA encoding SEQ ID NO:3. Therefore the rejection under 35 USC 103(a) stands.

Applicant also argues that certain parts of claim 14 recite mutations and therefore the claimed sequences are not obvious over the cited references. While the particular mutations may in fact be non-obvious, claim 14 part(c)(i) and claim 31 each are drawn to nucleic acids encoding SEQ ID NO:3, without any mutations. Therefore rejection of these claims is proper.

Rejections and Objections Necessitated by Amendment

4. Claim 30 is objected to because of the following informalities: the claim recites nucleic acid sequences greater than 10 nucleotides long, but does not recite the corresponding SEQ ID NO: to identify the sequence. The claims do not comply with 37 CFR 1.821(d). Careful inspection of the present version of claim 30, and that filed 28 March 2008, indicate that the two recited sequences are SEQ ID NO:190 and 192 respectively. Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 25 and 39 - 40 are is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 25, part (b), refers to "...the SCN1A subunits in (a)". It is clear that this refers to part (a) of some claim. However, it is unclear whether this refers to the SCN1A subunits of claim 25, part (a), or to those of parent claim 14, part (a), as claim 25 depends from claim 14, which also has multiple parts identified by letters. Claims 39 - 40 are also rejected as they depend from rejected claim 25 but do not clarify the scope of patent protection sought.

Conclusion

6. Claims 14, 17, 20, 25, 31, and 39 - 40 are rejected.

7. Claims 30 and 32 - 34 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANIEL KOLKER whose telephone number is (571)272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Daniel E. Kolker/
Primary Examiner, Art Unit 1649
March 5, 2009